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ELI LILLY AND COMPANY

By Linda M. Durbin Date March 22, 2006

PATENT APPLICATION
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	Richard Dennis DiMarchi, et al.	
Serial No.	:	10/516,490	
International Application Date	:	June 2, 2003	Confirmation No.: 8626
For	:	Modified Glucagon-Like Peptide-1 Analogs	
Docket No.	:	X-15642	

STATEMENT TO SUPPORT FILING AND SUBMISSION IN ACCORDANCE WITH 37 C.F.R. 1.821(f) (SEQUENCE LISTING)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I hereby affirm that the content of the paper and computer readable copies of the Sequence Listing, submitted in accordance with 37 C.F.R. 1.821(c) and (e), respectively, are the same.

Respectfully submitted,

Alejandro Martinez
Agent for Applicants
Registration No. 58,163
Phone: 317-277-4260

Eli Lilly and Company
Patent Division
P.O. Box 6288
Indianapolis, Indiana 46206-6288

March 22, 2006

50C

STIC Biotechnology Systems Branch

RAW SEQUENCE LISTING ERROR REPORT

The Biotechnology Systems Branch of the Scientific and Technical Information Center (STIC) detected errors when processing the following computer readable form:

Application Serial Number: 10/516,490A
Source: PCT/IB
Date Processed by STIC: 1/10/06

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Revised 01/24/05

PCT

RAW SEQUENCE LISTING DATE: 01/10/2006
PATENT APPLICATION: US/10/516,490A TIME: 08:39:08

Input Set : A:\X15642.NatlPhase.ST25.txt
Output Set: N:\CRF4\01102006\J516490A.raw

3 <110> APPLICANT: Richard Dennis DiMarchi
4 David Lee Smiley
5 Lianshan Zhang
7 <120> TITLE OF INVENTION: MODIFIED GLUCAGON-LIKE PEPTIDE-1 ANALOGS
9 <130> FILE REFERENCE: X-15642 National Phase
C--> 11 <140> CURRENT APPLICATION NUMBER: US/10/516,490A
C--> 11 <141> CURRENT FILING DATE: 2004-12-01
11 <160> NUMBER OF SEQ ID NOS: 24
13 <170> SOFTWARE: PatentIn version 3.2
15 <210> SEQ ID NO: 1
16 <211> LENGTH: 31
17 <212> TYPE: PRT
18 <213> ORGANISM: Artificial
20 <220> FEATURE:
21 <223> OTHER INFORMATION: Synthetic constructs
24 <220> FEATURE:
25 <221> NAME/KEY: MISC_FEATURE
26 <222> LOCATION: (1)..(1)
27 <223> OTHER INFORMATION: Xaa= L-histidine, D-histidine, desamino-histidine,
28 2-amino-histidine, beta-hydroxy-
29 histidine, homohistidine, alpha-fluoromethyl-histidine, or alpha
30 methyl-histidine
32 <220> FEATURE:
33 <221> NAME/KEY: MISC_FEATURE
34 <222> LOCATION: (2)..(2)
35 <223> OTHER INFORMATION: Xaa= Ala, Gly, Val, Leu, Ile, Ser, or Thr
37 <220> FEATURE:
38 <221> NAME/KEY: MISC_FEATURE
39 <222> LOCATION: (6)..(6)
40 <223> OTHER INFORMATION: Xaa= Phe, Trp, or Tyr
42 <220> FEATURE:
43 <221> NAME/KEY: MISC_FEATURE
44 <222> LOCATION: (10)..(10)
45 <223> OTHER INFORMATION: Xaa= Val, Trp, Ile, Leu, Phe, or Tyr
47 <220> FEATURE:
48 <221> NAME/KEY: MISC_FEATURE
49 <222> LOCATION: (12)..(12)
50 <223> OTHER INFORMATION: Xaa= Ser, Trp, Tyr, Phe, Lys, Ile, Leu, Val
52 <220> FEATURE:
53 <221> NAME/KEY: MISC_FEATURE
54 <222> LOCATION: (13)..(13)
55 <223> OTHER INFORMATION: Xaa= Tyr, Trp, or Phe
57 <220> FEATURE:

pr 2-3, 5-7

Does Not Comply
Corrected Diskette Needed

RAW SEQUENCE LISTING DATE: 01/10/2006
PATENT APPLICATION: US/10/516,490A TIME: 08:39:08

Input Set : A:\X15642.NatlPhase.ST25.txt
Output Set: N:\CRF4\01102006\J516490A.raw

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     60 <223> OTHER INFORMATION: Xaa= Leu, Phe, Tyr, or Trp
     62 <220> FEATURE:
     63 <221> NAME/KEY: MISC_FEATURE
     64 <222> LOCATION: (16)..(16)
     65 <223> OTHER INFORMATION: Xaa= Gly, Glu, Asp, Lys
     67 <220> FEATURE:
     68 <221> NAME/KEY: MISC_FEATURE
     69 <222> LOCATION: (19)..(19)
     70 <223> OTHER INFORMATION: Xaa= Ala, Val, Ile, or Leu
     72 <220> FEATURE:
     73 <221> NAME/KEY: MISC_FEATURE
     74 <222> LOCATION: (21)..(21)
     75 <223> OTHER INFORMATION: Xaa= Glu, Ile, or Ala
     77 <220> FEATURE:
     78 <221> NAME/KEY: MISC_FEATURE
     79 <222> LOCATION: (24)..(24)
     80 <223> OTHER INFORMATION: Xaa= Ala, or Glu
     82 <220> FEATURE:
     83 <221> NAME/KEY: MISC_FEATURE
     84 <222> LOCATION: (27)..(27)
     85 <223> OTHER INFORMATION: Xaa= Val, or Ile
     87 <220> FEATURE:
     88 <221> NAME/KEY: MISC_FEATURE
     89 <222> LOCATION: (31)..(31)
     90 <223> OTHER INFORMATION: Xaa= L-Cys, D-Cys, homocysteine, or penicillamine
     92 <400> SEQUENCE: 1
W--> 94 Xaa Xaa Glu Gly Thr Xaa Thr Ser Asp Xaa Ser Xaa Xaa Xaa Glu Xaa
     95 1               5                  10                  15
W--> 98 Gln Ala Xaa Lys Xaa Phe Ile Xaa Trp Leu Xaa Lys Gly Arg Xaa
     99             20                  25                  30
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    103 <211> LENGTH: 31
    104 <212> TYPE: PRT
    105 <213> ORGANISM: Artificial
    107 <220> FEATURE:
    108 <223> OTHER INFORMATION: Synthetic construct
    111 <220> FEATURE:
    112 <221> NAME/KEY: MISC_FEATURE
    113 <222> LOCATION: (1)..(1)
    114 <223> OTHER INFORMATION: Xaa= L-histidine, D-histidine, desamino-
histidine,
    115       2-amino-histidien, beta-hydroxy-
    116       histidine, homohistidine, alpha-fluoromethyl-histidine, or
    117       alpha-methyl-histidine
    119 <220> FEATURE:
    120 <221> NAME/KEY: MISC_FEATURE
    121 <222> LOCATION: (2)..(2)
    122 <223> OTHER INFORMATION: Xaa= Gly, Ala, Val, Leu, Ile, Ser or Thr
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RAW SEQUENCE LISTING DATE: 01/10/2006
PATENT APPLICATION: US/10/516,490A TIME: 08:39:08

Input Set : A:\X15642.NatlPhase.ST25.txt
Output Set: N:\CRF4\01102006\J516490A.raw

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     124 <220> FEATURE:
     125 <221> NAME/KEY: MISC_FEATURE
     126 <222> LOCATION: (10)..(10)
     127 <223> OTHER INFORMATION: Xaa = Val, Phe, Tyr, or Trp
     129 <220> FEATURE:
     130 <221> NAME/KEY: MISC_FEATURE
     131 <222> LOCATION: (12)..(12)
     132 <223> OTHER INFORMATION: Xaa = Ser, Tyr, Trp, Phe, Lys, Ile, Leu, or Val
     134 <220> FEATURE:
     135 <221> NAME/KEY: MISC_FEATURE
     136 <222> LOCATION: (16)..(16)
     137 <223> OTHER INFORMATION: Xaa = Gly, Clu Asp, or Lys
     139 <220> FEATURE:
     140 <221> NAME/KEY: MISC_FEATURE
     141 <222> LOCATION: (19)..(19)
     142 <223> OTHER INFORMATION: Xaa = Ala, Val, Ile, or Leu
     144 <220> FEATURE:
     145 <221> NAME/KEY: MISC_FEATURE
     146 <222> LOCATION: (27)..(27)
     147 <223> OTHER INFORMATION: Xaa = Val or Ile
     149 <220> FEATURE:
     150 <221> NAME/KEY: MISC_FEATURE
     151 <222> LOCATION: (31)..(31)
     152 <223> OTHER INFORMATION: Xaa = L-Cys, D-Cys, homocysteine, or
penicillamine
     154 <400> SEQUENCE: 2
W--> 156 Xaa Xaa Glu Gly Thr Phe Thr Ser Asp Xaa Ser Xaa Tyr Leu Glu Xaa
     157 1               5                   10                  15
W--> 160 Gln Ala Xaa Lys Glu Phe Ile Ala Trp Leu Xaa Lys Gly Arg Xaa
     161             20                  25                  30
     164 <210> SEQ ID NO: 3
     165 <211> LENGTH: 42
     166 <212> TYPE: PRT
     167 <213> ORGANISM: Artificial
     169 <220> FEATURE:
     170 <223> OTHER INFORMATION: Synthetic construct
     173 <220> FEATURE:
     174 <221> NAME/KEY: MISC_FEATURE
     175 <222> LOCATION: (1)..(1)
     176 <223> OTHER INFORMATION: Xaa = L-histidine, D-histidine, desamino-
histidine,
     177       2-amino-histidine, beta-hydroxy-
     178       histidine, homohistidine, alpha-fluoromethyl-histidine, or
     179       alpha-methyl-histidine
     181 <220> FEATURE:
     182 <221> NAME/KEY: MISC_FEATURE
     183 <222> LOCATION: (2)..(2)
     184 <223> OTHER INFORMATION: Xaa = Ala, Gly, Val, Leu, Ile, Ser, or Thr
     186 <220> FEATURE:
     187 <221> NAME/KEY: MISC_FEATURE
     188 <222> LOCATION: (6)..(6)
```

do you mean Glu?

RAW SEQUENCE LISTING DATE: 01/10/2006
PATENT APPLICATION: US/10/516,490A TIME: 08:39:08

Input Set : A:\X15642.NatlPhase.ST25.txt
Output Set: N:\CRF4\01102006\J516490A.raw

189 <223> OTHER INFORMATION: Xaa = Phe, Trp, or Tyr
191 <220> FEATURE:
192 <221> NAME/KEY: MISC_FEATURE
193 <222> LOCATION: (10)..(10)
194 <223> OTHER INFORMATION: Xaa = Val, Trp, Ile, Leu, Phe, or Tyr
196 <220> FEATURE:
197 <221> NAME/KEY: MISC_FEATURE
198 <222> LOCATION: (12)..(12)
199 <223> OTHER INFORMATION: Xaa = Ser, Trp, Tyr, Phe, Lys, Ile, Leu, Val
201 <220> FEATURE:
202 <221> NAME/KEY: MISC_FEATURE
203 <222> LOCATION: (13)..(13)
204 <223> OTHER INFORMATION: Xaa = Tyr, Trp, or Phe
206 <220> FEATURE:
207 <221> NAME/KEY: MISC_FEATURE
208 <222> LOCATION: (14)..(14)
209 <223> OTHER INFORMATION: Xaa = Leu, Phe, Tyr, or Trp
211 <220> FEATURE:
212 <221> NAME/KEY: MISC_FEATURE
213 <222> LOCATION: (16)..(16)
214 <223> OTHER INFORMATION: Xaa = Gly, Glu, Asp, or Lys
216 <220> FEATURE:
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218 <222> LOCATION: (19)..(19)
219 <223> OTHER INFORMATION: Xaa = Ala, Val, Ile, or Leu
221 <220> FEATURE:
222 <221> NAME/KEY: MISC_FEATURE
223 <222> LOCATION: (21)..(21)
224 <223> OTHER INFORMATION: Xaa = Glu, Ile, or Ala
226 <220> FEATURE:
227 <221> NAME/KEY: MISC_FEATURE
228 <222> LOCATION: (24)..(24)
229 <223> OTHER INFORMATION: Xaa = Ala or Glu
231 <220> FEATURE:
232 <221> NAME/KEY: MISC_FEATURE
233 <222> LOCATION: (27)..(27)
234 <223> OTHER INFORMATION: Xaa = Val or Ile
236 <220> FEATURE:
237 <221> NAME/KEY: MISC_FEATURE
238 <222> LOCATION: (28)..(28)
239 <223> OTHER INFORMATION: Xaa = Lys, Asp, Arg, or Glu
241 <220> FEATURE:
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243 <222> LOCATION: (30)..(30)
244 <223> OTHER INFORMATION: Xaa = Gly, Pro, or Arg
246 <220> FEATURE:
247 <221> NAME/KEY: MISC_FEATURE
248 <222> LOCATION: (31)..(31)
249 <223> OTHER INFORMATION: Xaa = Gly, Pro, Ser, L-Cys, D-Cys, homocysteine, or penicillamine

RAW SEQUENCE LISTING DATE: 01/10/2006
PATENT APPLICATION: US/10/516,490A TIME: 08:39:08

Input Set : A:\X15642.NatlPhase.ST25.txt
Output Set: N:\CRF4\01102006\J516490A.raw

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     252 <221> NAME/KEY: MISC_FEATURE
     253 <222> LOCATION: (32)..(32)
     254 <223> OTHER INFORMATION: Xaa = Ser, Pro, His, L-Cys, D-Cys, homocysteine,
penicillamine,
     255       NH2
     257 <220> FEATURE:
     258 <221> NAME/KEY: MISC_FEATURE
     259 <222> LOCATION: (33)..(33)
     260 <223> OTHER INFORMATION: Xaa = Ser, Arg, Thr, Trp, Lys, L-Cys, D-Cys,
homocysteine,
     261       penicillamine, NH2 or
     262       is absent
     264 <220> FEATURE:
     265 <221> NAME/KEY: MISC_FEATURE
     266 <222> LOCATION: (34)..(34)
     267 <223> OTHER INFORMATION: Xaa = Ser, Gly, L-Cys, D-Cys, homocysteine,
penicillamine, NH2,
     268       or is absent
     270 <220> FEATURE:
     271 <221> NAME/KEY: MISC_FEATURE
     272 <222> LOCATION: (35)..(35)
     273 <223> OTHER INFORMATION: Xaa = Ala, Asp, Arg, Glu, Lys, Gly, L-Cys, D-Cys,
homocysteine,
     274       penicillamine,
     275       NH2 or is absent
     277 <220> FEATURE:
     278 <221> NAME/KEY: MISC_FEATURE
     279 <222> LOCATION: (36)..(36)
     280 <223> OTHER INFORMATION: Xaa = Pro, Ala, L-Cys, D-Cys, homocysteine,
penicillamine, NH2,
     281       or is absent
     283 <220> FEATURE:
     284 <221> NAME/KEY: MISC_FEATURE
     285 <222> LOCATION: (37)..(37)
     286 <223> OTHER INFORMATION: Xaa = Pro, Ala, L-Cys, D-Cys, homocysteine,
penicillamine, NH2 or
     287       is absent
     289 <220> FEATURE:
     290 <221> NAME/KEY: MISC_FEATURE
     291 <222> LOCATION: (38)..(38)
     292 <223> OTHER INFORMATION: Xaa = Pro, Ala, Arg, Lys, His, L-Cys, D-Dys,
homocysteine,
     293       penicillamine, NH2 or
     294       is absent
     296 <220> FEATURE:
     297 <221> NAME/KEY: MISC_FEATURE
     298 <222> LOCATION: (39)..(39)
     299 <223> OTHER INFORMATION: Xaa = Ser, His, Pro, Lys, Arg, L-Cys, D-Cys,
homocysteine,
     300       penicillamine, NH2 or
     301       is absent
     303 <220> FEATURE:
```

do you mean "amidation?" If so, please add "amidated" to "NH_2"

Cys?

304 <221> NAME/KEY: MISC_FEATURE
305 <222> LOCATION: (40)..(40)
306 <223> OTHER INFORMATION: Xaa = His, Ser, Arg, Lys, L-Cys, D-Cys,
homocysteine,
307 penicillamine, NH2 or

Please ensure that amino acids are spelled correctly in subsequent sequences.

RAW SEQUENCE LISTING ERROR SUMMARY DATE: 01/10/2006
PATENT APPLICATION: US/10/516,490A TIME: 08:39:09

Input Set : A:\X15642.NatlPhase.ST25.txt
Output Set: N:\CRF4\01102006\J516490A.raw

FYI

Please Note:
Use of n and/or Xaa have been detected in the Sequence Listing. Please review the Sequence Listing to ensure that a corresponding explanation is presented in the <220>
to <223> fields of each sequence which presents at least one n or Xaa.

Seq#:1; Xaa Pos. 1,2,6,10,12,13,14,16,19,21,24,27,31
Seq#:2; Xaa Pos. 1,2,10,12,16,19,27,31
Seq#:3; Xaa Pos. 1,2,6,10,12,13,14,16,19,21,24,27,28,30,31,32,33,34,35,36
Seq#:3; Xaa Pos. 37,38,39,40,41,42
Seq#:4; Xaa Pos. 1,2,10,16,19,27,28,30,31,32,33,34,35,36,37,38,39,40,41,42
Seq#:5; Xaa Pos. 1,2,16,19,27,32,33,34,35,36,37,38,39,40,41,42
Seq#:6; Xaa Pos. 1,2,6,10,12,13,14,16,19,21,24,27,28,30,31,32,33,34,35,36
Seq#:6; Xaa Pos. 37,38,39,40,41,42,43,44,45
Seq#:7; Xaa Pos. 32,33,34,35,36,37,38,39,40,41,42,43,44,45
Seq#:8; Xaa Pos. 1,2,6,10,12,13,14,16,19,21,24,27
Seq#:9; Xaa Pos. 1,2,10,12,16,19,27
Seq#:10; Xaa Pos. 1,2,6,10,12,13,14,16,19,21,24,27,28,30,31,32,33,34,35,36
Seq#:10; Xaa Pos. 37,38,39,40,41,42
Seq#:11; Xaa Pos. 1,2,10,16,19,27,28,30,31,32,33,34,35,36,37,38,39,40,41,42
Seq#:12; Xaa Pos. 1,2,16,19,27,32,33,34,35,36,37,38,39,40,41,42
Seq#:13; Xaa Pos. 1,2,6,10,12,13,14,16,19,21,24,27,28,30,31,32,33,34,35,36
Seq#:13; Xaa Pos. 37,38,39,40,41,42,43,44,45
Seq#:14; Xaa Pos. 32,33,34,35,36,37,38,39,40,41,42,43,44,45
Seq#:15; Xaa Pos. 1,2,6,10,12,13,14,16,19,21,24,27,31

Invalid <213> Response:
Use of "Artificial" only as "<213> Organism" response is incomplete, per 1.823(b) of New Sequence Rules. Valid response is Artificial Sequence.

Seq#:1,2,3,4,5,6,7,8,9,10,11,12,13,14,15,16,17,18,19,20,21,22

VERIFICATION SUMMARY DATE: 01/10/2006
PATENT APPLICATION: US/10/516,490A TIME: 08:39:09

Input Set : A:\X15642.NatlPhase.ST25.txt
Output Set: N:\CRF4\01102006\J516490A.raw

L:11 M:270 C: Current Application Number differs, Replaced Current Application No
L:11 M:271 C: Current Filing Date differs, Replaced Current Filing Date
L:94 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:1 after pos.:0
L:98 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:1 after pos.:16
L:156 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:2 after pos.:0
L:160 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:2 after pos.:16
L:324 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:3 after pos.:0
L:328 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:3 after pos.:16
L:332 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:3 after pos.:32
L:466 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:4 after pos.:0
L:470 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:4 after pos.:16
L:474 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:4 after pos.:32
L:583 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:5 after pos.:0
L:587 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:5 after pos.:16
L:591 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:5 after pos.:32
L:762 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:6 after pos.:0
L:766 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:6 after pos.:16
L:770 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:6 after pos.:32
L:869 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:7 after pos.:16
L:873 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:7 after pos.:32
L:951 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:8 after pos.:0
L:955 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:8 after pos.:16
L:1008 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:9 after pos.:0
L:1012 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:9 after pos.:16
L:1160 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:10 after pos.:0
L:1164 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:10 after pos.:16
L:1168 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:10 after pos.:32
L:1286 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:11 after pos.:0
L:1290 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:11 after pos.:16
L:1294 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:11 after pos.:32
L:1391 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:12 after pos.:0
L:1395 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:12 after pos.:16
L:1399 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:12 after pos.:32
L:1561 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:13 after pos.:0
L:1565 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:13 after pos.:16
L:1569 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:13 after pos.:32
L:1658 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:14 after pos.:16
L:1662 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:14 after pos.:32
L:1745 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:15 after pos.:0
L:1749 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:15 after pos.:16